

Applicant : Riccardo Dalla Favera
Serial No.: 09/724,254
Filed : November 28, 2000
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REMARKS

Claims 1-25, 33-47, 69 and 70 are pending and under examination in the subject application. By this Amendment, applicant has canceled claims 1-25, 32-42 and 44, and amended claim 43. Support for amended claim 43 may be found in the specification *inter alia* at page 40, lines 27-31; page 41, line 1 to page 43, line 7; page 66, line 21 to page 67, line 21; in Figures 18B1-B3 and SEQ ID NOs. 44, 3 and 41. Accordingly, claims 43-47, 69 and 70 will be pending and under examination in the subject application upon entry of this Amendment.

In view of the remarks below, applicant maintains that the Examiner's rejections have been overcome, and respectfully requests that they be withdrawn.

Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 43-47, 69 and 70 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleges that the genus of proteins is highly varied as structural attributes which define the proteins of the genus are missing from the claims.

In response to the rejection of claim 44, applicant notes that this claim has been canceled rendering the rejection moot.

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In response to the rejection of the remaining claims, but without conceding the correctness of the Examiner's rejection, applicant notes that as amended, independent claim 43 provides antibodies directed to an IRTA2 protein, wherein the protein is one of the three isoforms of IRTA2 sequences, namely SEQ ID NOs. 44, 3 or 41. The instant specification provides a description of these three isoforms of IRTA2, *inter alia*, at page 66, line 21 to page 67, line 21, shown in Figures 18B1-B3 and SEQ ID NOs. 44, 3 and 41.

In view of these remarks, applicant maintains that amended claim 43 and dependent claims 45-47, 69 and 70 are adequately supported by the disclosure and satisfy the requirements of 35 U.S.C. §112, first paragraph.

Rejection Under 35 U.S.C. §102(b)

The Examiner rejected claims 43, 44 and 69 under 35 U.S.C. §102(b) as allegedly anticipated by the abstract of Medesan et al. Specifically, the Examiner alleges that Medesan et al. disclose heat aggregated human serum IgG, thus fulfilling the specific embodiments of the claims.

In response to the rejection of claim 44, applicant notes that this claim has been canceled rendering the rejection moot.

In response to the rejection of the remaining claims, but without conceding the correctness of the Examiner's rejection, applicant notes that as amended, independent claim 43 provides antibodies directed to an IRTA2 protein, wherein the protein is one of the three isoforms of IRTA2 sequences, namely SEQ ID

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NOs. 44, 3 or 41, the amino acid sequences of the three isoforms of IRTA2..

Under 35 U.S.C. §102(b), a person shall be entitled to a patent unless "the invention was patented or described in a printed publication in this or a foreign country", more than one year prior to the date of filing the application for patent. According to M.P.E.P. §2131, "[t]o anticipate a claim, the reference must teach every element of the claim."

Medesan et al. do not teach an antibody directed to human IRTA2 protein as claimed, but instead suggests that two types of Fc receptors bind to heat aggregated human serum IgG. The Examiner further alleges that as defined in claim 43, IRTA2 may be an Fc receptor. Applicant notes that as amended, claim 43 specifically defines the IRTA2 protein as having the disclosed amino acid sequence of any of the three listed isoforms of IRTA2. Medesan et al. do not teach, either explicitly or inherently, the epitopes or any amino acid sequence of the Fc receptors to which the heat aggregated human serum IgG bind. Therefore, Medesan et al. do not teach each and every element of the rejected claims

The Examiner further rejected claims 43-46 under 35 U.S.C. §102(b) as allegedly anticipated by Zipf et al. as evidenced by the abstract of Callahan et al. and Macardle et al. Specifically, the Examiner alleges that Zipf et al. disclose a monoclonal antibody of 41H.16 and Macardle teaches that the 41H.16 antibody is an anti-CD32 that binds to FcγmmRIIb. Callahan et al. teaches overexpression of FcγmmRIIb2 in a follicular lymphoma cell line exhibiting a 1q21 translocation.

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In response to the rejection of claim 44, applicant notes that this claim has been canceled rendering the rejection moot.

In response to the rejection of claims 43, 45 and 46 applicant respectfully traverses. Without conceding the correctness of the Examiner's rejection, applicant again notes that as amended, independent claim 43 provides antibodies directed to an IRTA2 protein, wherein the protein is one of the three isoforms of IRTA2 sequences, namely SEQ ID NOs. 44, 3 or 41, the amino acid sequences of the three isoforms of IRTA2.

Applicant again maintains that as amended claim 43 clearly defines the IRTA2 isoform to which the claimed antibody binds. Neither Zipf et al. as evidenced by Callahan et al. and Macardle et al. nor Medesan et al. disclose the elements of the rejected claims, namely they do not disclose the amino acid sequence of the IRTA2 protein isotype. Accordingly, applicant maintains that claims 43, 45 and 46 are not anticipated by the cited references.

In view of these remarks, applicant maintains that amended claim 43 and dependent claims 45, 46 and 69 satisfy the requirements of 35 U.S.C. §102(b).

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 43-47 under 35 U.S.C. §103(a) as allegedly unpatentable over Schlom in view of Zipf et al., the abstract of Callahan et al., Macardle et al. and Latour et al.

In response to the rejection of claim 44, applicant notes that

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this claim has been canceled rendering the rejection moot.

In response to the rejection of claims 43, 45 and 46 applicant respectfully traverses. Without conceding the correctness of the Examiner's rejection, applicant again notes that as amended, independent claim 43 provides antibodies directed to an IRTA2 protein, wherein the protein is one of the three isoforms of IRTA2 sequences, namely SEQ ID NOs. 44, 3 or 41, the amino acid sequences of the three isoforms of IRTA2.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate three criteria with respect to each claim. First, the cited references, when combined, teach or suggest every element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited reference at the time of the invention. And third, there would have been a reasonable expectation that the claimed invention would succeed.

In light of these requirements, applicant maintains that the cited references fail to support a *prima facie* case of obviousness for claims 43 and 45-47.

The cited references, in combination, fail to teach all elements of amended claim 43. In particular, these references fail to teach the IRTA2 isotype which defines the protein to which the claimed antibody binds.

According to the Examiner, Schlom teaches anti-tumor antibodies conjugated to drugs; Latour et al. teach that antibodies which bind to FcgammaRIIb2 are internalized; and

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the combination of Zipf et, the abstract of Callahan et al. and Macardle et al. teach that the anti-CD32 antibody binds to the FcgammaRIIb2 receptor which is overexpressed in a cell line derived from a lymphoma patient. None of these references teaches the IRTA2 isotype as defined in amended claim 43.

For the reasons above, the cited references combined fail to teach the elements of the claimed assay. Absent such teaching, there could not have been a motive to combine or a reasonable expectation of success.

In view of the above remarks, applicant maintains that the Examiner has failed to set forth a *prima facie* case of obviousness, and that accordingly, claims 43, 45-47, 69 and 70 satisfy the requirements of 35 U.S.C. §103(a).

Summary

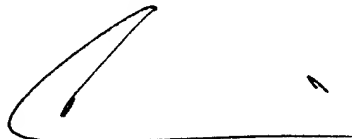
For the reasons set forth hereinabove, applicant respectfully requests that the Examiner reconsider and withdraw the rejections, and solicits allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

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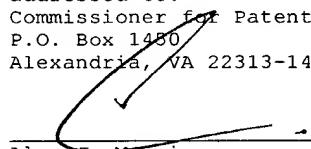
No fee is deemed necessary in connection with the filing of this Amendment. However if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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8/7/07 Date